

**§ 822.9 What must I include in my submission?**

Your submission must include the following:

- (a) Organizational/administrative information:
  - (1) Your name and address;
  - (2) Generic and trade names of your device;
  - (3) Name and address of the contact person for the submission;
  - (4) Premarket application/submission numbers for your device;
  - (5) Table of contents identifying the page numbers for each section of the submission;
  - (6) Description of the device (this may be incorporated by reference to the appropriate premarket application/submission);
  - (7) Product codes and a list of all relevant model numbers; and
  - (8) Indications for use and claims for the device;
- (b) Postmarket surveillance plan;
- (c) Designated person information:
  - (1) Name, address, and telephone number; and
  - (2) Experience and qualifications.

**§ 822.10 What must I include in my surveillance plan?**

Your surveillance plan must include a discussion of:

- (a) The plan objective(s) addressing the surveillance question(s) identified in our order;
- (b) The subject of the study, e.g., patients, the device, animals;
- (c) The variables and endpoints that will be used to answer the surveillance question, e.g., clinical parameters or outcomes;
- (d) The surveillance approach or methodology to be used;
- (e) Sample size and units of observation;
- (f) The investigator agreement, if applicable;
- (g) Sources of data, e.g., hospital records;
- (h) The data collection plan and forms;
- (i) The consent document, if applicable;
- (j) Institutional Review Board information, if applicable;
- (k) The patient followup plan, if applicable;

- (l) The procedures for monitoring conduct and progress of the surveillance;

- (m) An estimate of the duration of surveillance;

- (n) All data analyses and statistical tests planned;

- (o) The content and timing of reports.

**§ 822.11 What should I consider when designing my plan to conduct postmarket surveillance?**

You must design your surveillance to address the postmarket surveillance question identified in the order you received. You should consider what, if any, patient protection measures should be incorporated into your plan. You should also consider the function, operating characteristics, and intended use of your device when designing a surveillance approach.

**§ 822.12 Do you have any information that will help me prepare my submission or design my postmarket surveillance plan?**

Guidance documents that discuss our current thinking on preparing a postmarket surveillance submission and designing a postmarket surveillance plan are available on the Center for Devices and Radiological Health's Web site and from the Center for Devices and Radiological Health, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Dr., Rockville, MD 20850. Guidance documents represent our current interpretation of, or policy on, a regulatory issue. They do not establish legally enforceable rights or responsibilities and do not legally bind you or FDA. You may choose to use an approach other than the one set forth in a guidance document, as long as your alternative approach complies with the relevant statutes (laws) and regulations. If you wish, we will meet with you to discuss whether an alternative approach you are considering will satisfy the requirements of the act and regulations.